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Mi Kyong Shin

PATENT

Attorney Docket No. 12636.219

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application)

PATENT APPLICATION

Inventor(s): Jorge DIMARTINO et al.)

Art Unit: 1623

Application No.: 09/976,468)

Examiner: Patrick T. Lewis

Filed: October 12, 2001)

Title: Composition and method for treating
graft-versus-host disease)

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Commissioner of Patents

P.O. Box 1450

Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97

Sir:

Applicants hereby submit an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is being submitted herewith, along with a concise explanation of information in a foreign language, if any, pursuant to 37 C.F.R. §1.97-1.98.

Applicants respectfully request that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicants further request that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicants reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

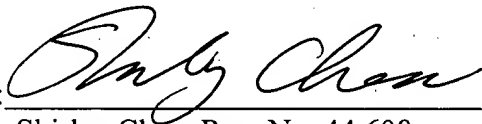
- ☐ This statement qualifies under 37 C.F.R. §1.97, subsection (b) because:
- ☐ (1) It is being filed within 3 months of the application filing date and is other than a continued prosecution application under § 1.53(d)
-- OR --
 - ☐ (2) It is being filed within 3 months of entry of a national stage
-- OR --
 - ☐ (3) It is being filed before the mail date of the first Office Action on the merits
-- OR --
 - ☐ (4) It is being filed before the mailing of a first Office Action after the filing of a request for continued examination under § 1.114.
- ☒ 37 C.F.R. §1.97(c). If this statement is being filed after the latest of: (1) three months beyond the filing date of a national application; (2) three months beyond the date of entry of the national stage as set forth in §1.491 in an international application; or (3) the mailing date of a first Office action on the merits, but before the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, then:
- ☐ a certification as specified in §1.97(e) is provided below; or
 - ☒ a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☐ 37 C.F.R. §1.97(d). If this statement is being filed after the mailing date of the earlier of a final office action under §1.113 or a notice of allowance under §1.311, but before payment of the issue fee, then:
- A. a certification as specified in §1.97(e) is completed below; and
 - B. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- ☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.
- ☒ Copies of references listed on the attached Form PTO/SB/08 are enclosed herewith EXCEPT THAT:
- ☐ In view of the voluminous nature of references, and the likelihood that these references are available to the Examiner in the file history of the parent application (Serial No.), copies are not enclosed herewith.
 - ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.
 - ☒ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed.)

- ☐ There are no listed references which are not in the English language.
- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☐ Attached are copies of search report(s) from corresponding patent application(s), submitted in accordance with MPEP 609 D in support of the attached certification under 37 CFR 1.97(e)(1).
- ☐ Attached are the following non-published pending patent applications which may be deemed relevant.
- ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$180.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No.12636.219).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: June 21, 2005

By: 
Shirley Chen, Reg. No. 44,608

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Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	09/976,468
				Filing Date	10/12/2001
				First Named Inventor	DiMartino et al.
				Art Unit	1623
				Examiner Name	Lewis
Sheet	1	of	4	Attorney Docket Number	12636.219

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		APPELBAUM, F., "Allogeneic Stem-Cell Transplantation for Hematological Malignancies", 1 ed. <i>Medical Management of Hematological Malignant Diseases</i> , ed. E. Freireich. Vol. 1. 1998, New York: Marcel Dekker. 572.	
		ARMITAGE, J., "Bone Marrow Transplantation", <i>The New England Journal of Medicine</i> , (1994). 330(12):827-838.	
		BAGASRA, O. et al., "Adenosine-deaminase-associated immunodeficiency. I. Differential sensitivities of lymphocyte subpopulations exposed to 2-deoxycoformycin in vivo", <i>Clinical & Experimental Immunology</i> , (1992), 88(3):383-388.	
		BEATTY, P. et al., "Marrow transplantation from HLA-matched unrelated donors for treatment of hematologic malignancies", <i>Transplantation</i> , (February 1991), 51(2):443-447.	
		BOLANOS-MEADE, J. et al., "Pentostatin in steroid-refractory acute graft-versus-host disease", <i>Journal of Clinical Oncology</i> , (April 20, 2005), 23(12):2661-2668.	
		CATOVSKY, D. "Clinical experience with 2'-deoxycoformycin", <i>Hematology & Cell Therapy</i> , (1996), 38(S2):S103-S107.	
		CATOVSKY, D. et al., "Long term results with 2'deoxycoformycin in hairy cell leukemia", <i>Leukemia & Lymphoma</i> , (1994). 14(S1):109-113.	
		CUMMINGS, F.J. et al., "Phase II trial of pentostatin in refractory lymphomas and cutaneous T-cell disease", <i>Journal of Clinical Oncology</i> , (April 1991), 9(4):565-571.	
		EPSTEIN J. et al., "Prevention of graft-versus-host disease in allogeneic bone marrow transplantation by pretreatment with 2'-deoxycoformycin", <i>Experimental Hematology</i> , 1986. 14(9): p. 845-849.	
		FERRARA, J., "Cytokine Inhibitors and Graft-versus-Host Disease", <i>Annals New York Academy of Sciences</i> , (December 29, 1995), 770:227-236.	

Examiner signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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		FOSS, F.M. et al., "Phase II study of pentostatin and intermittent high-dose recombinant interferon alfa-2a in advanced mycosis fungoides/Sezary syndrome", <i>Journal of Clinical Oncology</i> , (December 1987), 10(12):1907-1913.	
		GIBLETT, E.R. et al., "Adenosine-deaminase Deficiency in Two Patients With Severely Impaired Immunity", <i>Lancet</i> , (November 18, 1972). 2:1067-1069.	
		GREVER, M. et al., "Optimal treatment for untreated patients with hairy cell leukemia?", 1996 ASCO Abstract Form, <i>Journal of Clinical Oncology</i> , (October 1995), 13(10):2677-2679.	
		GREVER M. et al., "Randomized comparison of pentostatin versus interferon alfa-2a in previously untreated patients with hairy cell leukemia: an intergroup study", Comment in: <i>J Clin Oncol.</i> , (October 13, 1995), 13(10):2677-2679.	
		GREVER, M. et al., "Low dose doxycoformycin in lymphoid malignancy", <i>Journal Clinical Oncology</i> , (September 1985), 3(9):1196-1201.	
		GREVER, M.R. et al., "Clinical Pharmacokinetics of 2-Deoxycoformycin in Renal Impairment", <i>Proceedings of ASCO</i> , (1993), 12(361):140.	
		GREVER, M.R. et al., "Inhibition of K and NK Lymphocyte Cytotoxicity by an Inhibitor of Adenosine Deaminase and Deoxyadenosine", <i>The Journal Of Immunology</i> , (December 1982), 129(6):365-369.	
		KHOURI, I.F. et al., "Allogeneic blood or marrow transplantation for chronic lymphocytic leukemia: timing of transplantation and potential effect of fludarabine on acute graft-versus-host disease", <i>British Journal of Hematology</i> , (May 1997), 97(2):466-473.	
		KOLB, H-J et al., "Graft-versus-leukemia effect of donor lymphocyte transfusions in marrow grafted patients", <i>Blood</i> , (September 1, 1995), 86(5):2041-2050.	
		KRAUT, E.H. et al., "Immunosuppressive effects of pentostatin", <i>Journal of Clinical Oncology</i> , (1990), 8(5):848-855.	
		KRAUT, E.H. et al., "Low-Dose Deoxycoformycin in the Treatment of Hairy Cell Leukemia", <i>Blood</i> , (1986). 68(5):1119-1122.	

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Sheet	3	of	4	Attorney Docket Number	12636.219

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		KRAUT, E.H. et al., "Pentostatin in the Treatment of Advanced Hairy Cell Leukemia", <i>Journal of Clinical Oncology</i> , (1989), 7(2):168-172.	
		LEE, S.J., "New approaches for preventing and treating chronic graft-versus-host disease", <i>Blood</i> , (June 2005), 105(11):4200-4206.	
		MARGOLIS, J. et al., ASH (1999), <i>Blood</i> , 94 # 10 Suppl 1 abstract 4878.	
		MARGOLIS, J. et al., ASH (2000), <i>Blood</i> 96 #11 abstract 1723.	
		MARTIN, P.J. et al., "A retrospective analysis of therapy for acute graft-versus-host disease: initial treatment", <i>Blood</i> , (October 15, 1990), 76(8):1464-1472.	
		MARTIN, P.J. et al., "A retrospective analysis of therapy for acute graft-versus-host disease: secondary treatment", <i>Blood</i> , (April 15, 1991), 77(8):1821-1828.	
		MONFARDINI, S. et al., "Pentostatin (2'-deoxycoformycin, dCF) in patients with low-grade (B-T-cell) and intermediate- and high-grade (T-cell) malignant lymphomas: phase II study of the EORTC Early Clinical Trials Group", <i>Oncology</i> , 1996. 53(2):163-168.	
		NASH, R.A. et al., "Acute graft-versus-host disease: analysis of risk factors after allogeneic marrow transplantation and prophylaxis with cyclosporine and methotrexate", <i>Blood</i> , (October 1, 1992), 80(7):1838-1845.	
		OR, R. et al., "Fludarabine monophosphate reduces the incidence and severity of graft-versus-host disease in a murine model of bone marrow transplantation", <i>Blood</i> , (July 1, 1997), 90(1):471-476.	
		PRZEPIORKA, D. et al., "Consensus Conference on Acute GVHD Grading", <i>Bone Marrow Transplantation</i> , (June 1995), 15(6):825-828.	
		RUERS, T.J.M. et al., "Inhibition of Lymphocyte-Specific Enzymes: A Promising Approach for Selective Immunosuppression", <i>Transplantation Proceedings</i> , (February 1987), 19(1):1287-1289.	

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		SAVEN, A. et al., "Newer purine analogues for the treatment of hairy-cell leukemia", <i>New England Journal of Medicine</i> , (March 10, 1994). 330(10):691-697.	
		SEYMOUR, J.F. et al., "Response duration and recovery of CD4+ lymphocytes following deoxycoformycin in interferon-alpha-resistant hairy cell leukemia: 7-year follow-up", <i>Leukemia</i> , (1997), 11(1):42-47.	
		STEIS, R.G. et al., "Kinetics of recovery of CD4+ T cells in peripheral blood of deoxycoformycin-treated patients", <i>Journal of the National Cancer Institute</i> , (November 20, 1991), 83(22):1678-1679.	
		URBA, W.J. et al., "Deoxycoformycin-Induced Immunosuppression in Patients With Hairy Cell Leukemia", <i>Blood</i> , (January 1989), 73(1):38-46.	
		VOGELSANG, G. et al., "Graft-Versus-Host Disease: New Directions for a Persistent Problem", <i>Blood</i> , (October 1, 1994), 84(7):2061-2067.	

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